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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,365	11/12/1999	Yongliang Chu	0942.4650001	9217

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

21

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/438,365

Applicant(s)

CHU ET AL

Examiner

Janet L Epps-Ford, Ph.D.

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-- Th MAILING DATE of this communication appears on the cov r she t with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 and 111-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 15, 20, 21, 29, 42, 45, 48, 63, 70, 77, 93-109 and 113-116 is/are rejected.
- 7) ☒ Claim(s) 10, 12-14, 16-19, 22-28, 30-41, 43, 44, 46, 47, 49-62, 64-69, 71-76, 78-92, 111 and 112 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-2-02 has been entered.

3. Applicant's arguments with respect to claims 1-9, 11, 15, 20-21, 29, 42, 45, 48, 63, 70, 77, 93, and 95-110 are moot in view of the following new grounds of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 97-100 and 113-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 97-100 recite a compound or a polycation that recites the variables "b" and "c." However, the structures recited in these claims are vague and indefinite since there is no definition given for these variables.

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Claims 113-116 recite "wherein Z is selected from the group consisting of spermyl, spermidyl, amino acid, peptidyl, diaminoalkyl, and polyamine when Z is part of any of the groups $-(CH_2)_bNHC(O)Z$, $-(CH_2)_cNHC(O)Z$, $-CH_2CH(OR_7)CH_2NHC(O)Z$, or $-CH_2CH(OR_8)CH_2NHC(O)Z$." First it is noted that the exact structures of the groups according to $-(CH_2)_bNHC(O)Z$, $-(CH_2)_cNHC(O)Z$, $-CH_2CH(OR_7)CH_2NHC(O)Z$, and $-CH_2CH(OR_8)CH_2NHC(O)Z$, are unclear since the manner in which these groups are covalently attached to the Z groups are not clearly set forth in either the specification or the claims. Additionally, the exact structure of the groups which define "Z," namely "spermyl, spermidyl, amino acid, peptidyl, diaminoalkyl, and polyamine," are not clearly set forth so that one of ordinary skill would be able to clearly understand how the Z group defines "part of" the structures according to $-(CH_2)_bNHC(O)Z$, $-(CH_2)_cNHC(O)Z$, $-CH_2CH(OR_7)CH_2NHC(O)Z$, and $-CH_2CH(OR_8)CH_2NHC(O)Z$. Therefore, it is unclear how one would adequately distinguish the claimed invention from potential infringement. It is recommended that applicants, for example, amend the claims to properly indicate the nature of the chemical bond between the C(O) moiety of these structures and that of the Z group, in particular Applicants should point out which atom is involved in this covalent attachment.

It is noted that the groups according to $-(CH_2)_bNHC(O)Z$, and $-(CH_2)_cNHC(O)Z$ are not mutually exclusive, and redundant since the definitions of the terms "b" and "c" are identical. Additionally the groups according to $-CH_2CH(OR_7)CH_2NHC(O)Z$, and $-CH_2CH(OR_8)CH_2NHC(O)Z$, are also redundant since the R_7 and R_8 terms are identical.

6. Claims 1-9, 11, 15, 20-21, 29, 42, 45, 48, 63, 70, 77, 93, and 95-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The structures recited in the instant claims require that the Q term is positively charged, i.e. Q^+ . However, the definitions of the individual variables in these structures encompass wherein the Q moiety would not be positively charged. For example, in claim 93, the definitions of m, n, r, s, u, v, w, and y are 0 or 1, with the proviso that when both m and n are 0 at least one of r, s, u, and y is other than 0. Therefore, for example, when m and n are both 0, both Q moieties in the claimed compound would not comprise a positive charge. Applicants have not properly described the full scope of compounds encompassed by the claimed invention, particularly wherein Q is positively charged and wherein any of m, n, r, s, u, v, w, or y is 0.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

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In the instant case, Applicants have not clearly set forth that the full scope of the claimed invention has actually been reduced to practice prior to filing of the instant application. It appears that further experimentation would be required in order to identify compounds according to the present invention wherein Q is positively charged and wherein any of m, n, r, s, u, v, w, or y is 0, since they are not described in the specification as filed. Therefore, the applicants were not in possession of the full scope of the claimed compounds since the invention was not "ready for patenting" at the time the invention was filed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-2, 5, 9, 29, 42 and 93-97, and 101-109 are rejected under 35 U.S.C. 102(a) as being anticipated by Haces et al.

Claims 1-2, 5, 9 and 93-98 are drawn to the genus of compounds encompassed by the formula as recited in claim 93. Haces et al., for example, discloses the compound according to (5a) (see page 6), this compound is encompassed by the formula recited in claims 1-2, 5, 9 and 93. Claim 29 is drawn to a compound according to the formula recited in claim 29. Compound 9 of Haces et al. recited in Scheme II is a species of the genus of compounds encompassed by the formula recited in claim 29. The compounds according to formula (I) recited on page 4 of Haces et al. are a species of the genus of compounds recited in claim 42 of the instant application. See also the compounds according to 4d-5a, 5b, and 5e in Scheme I of Haces et al., in particular note

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the definitions given for R2 that define the NH₂ amino terminal groups. (The following addresses claims 11-109) Haces et al. also disclose the use of the disclosed cationic compounds as nucleic acid transfection agents, and furthermore describe complexes of these polycationic lipids with nucleic acid (see page 4, and 2nd paragraph of page 6). Additionally, Haces et al. teach liposome formulations comprising the compounds of the Haces et al. invention and DOPE (see page 18, example 19), and the transfection of plasmids into cells using these liposome formulations (see example 20).

Haces et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Double Patenting

9. Applicant is advised that should claims 25-26 be found allowable, claims 27-28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Applicant is advised that should claims 33-34 be found allowable, claims 35-36 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Conclusion

11. Claims 10, 12-14, 16-19, 22-28, 30-41, 43, 44, 46, 47, 49-62, 64-69, 71-76, 78-92, 111 and 112 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12.

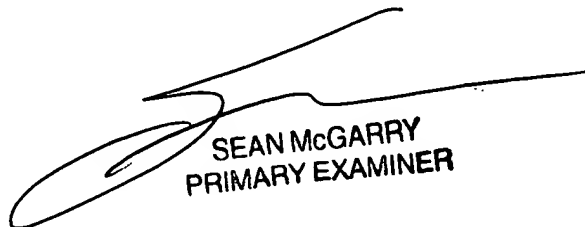
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
January 27, 2003


SEAN MCGARRY
PRIMARY EXAMINER